FINDING OF NO SIGNIFICANT IMPACT FOR

Food Additive Petition 0A4705, submitted by Alcide Corporation, to amend the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on poultry carcass parts.

The Chemistry and Environmental Review Team, Division of Product Policy, Center for Food Safety and Applied Nutrition, has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment and in a supplemental letter.

Prepared and Approved by:

Jordt Man Iles

Jeanette Glover Glew, Environmental Scientist Chemistry and Environmental Review Team

Division of Product Policy

99F-5523

FONS-1

Date: January 27, 2000

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January 10, 2000

Dr. Robert L. Martin
Office of Premarket Approval
Center for Food Safety & Applied Nutrition
Food and Drug Administration
200 C Street, S.W. (HFS-215)
Washington, D.C. 20204

RE: FAP 0A4705

Dear Dr. Martin:

Alcide Corporation hereby amends the Environmental Assessment (EA) portion (Section H) of the above-reference petition, in accordance with the guidance provided by your office.

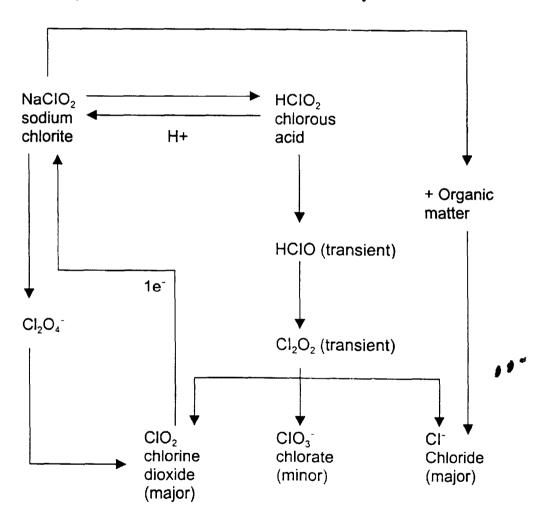
- 1) Alcide believes that no extraordinary circumstances will exist at any of the sites of production or use of the subject additive, Acidified Sodium Chlorite, that will create situations inconsistent with the projected environmental releases and emission compliance requirements (21 CFR 25.21).
- 2) Please include the following statement as an amendment to Format Item 6.2.3.:

We note that food-processing facilities that directly discharge process waters into surface waters must also obtain the appropriate permits and approvals. The use and discharge of an antimicrobial agent at point sources in the United States are subject to the requirements of National Pollution Discharge Elimination System (NPDES) permits under the Clean Water Act (33 U.S.C. 1251 et seq.). Users of the antimicrobial agent must not; 1) discharge the product into lakes, streams and ponds, estuaries, oceans, or other waters unless the discharge is in accordance with the requirements of an NPDES permit, and the user has notified the permitting authority in writing prior to discharge, and; 2) discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority.

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3) Please include the following diagram illustrating the various degradation pathways for acidified sodium chlorite in Format Item 7, to facilitate understanding of this complex system.

Schematic of Chlorite/Chlorous Acid System



Yours sincerely,

G. Kere Kemp Executive Vice President Chief Scientific Officer

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